

REMARKS

Claims 1, 4–16, 29, and 30 are pending in this application. Claims 1 and 4–16 are currently amended. Claims 2 and 3 are cancelled. Claims 17–28 are withdrawn.

Claims 29 and 30 are new

Claims 5–7, 9, 11, 13, and 15 are rejected under 35 U.S.C 112, second paragraph.

In light of the foregoing amendments to the claims, the Applicant respectfully requests that the §112, second paragraph, rejection of claims 5–7, 9, 11, 13, and 15 be reconsidered and withdrawn.

Claims 1–4 and 6–16 are rejected under 35 U.S.C. 112, first paragraph. The Examiner argues that the phrase “extract of red vine leaves” is not described in the specification in accordance with §112, first paragraph. In particular, the Examiner states that the present application lacks a representative number of examples “in order to reasonably verify possession of such a potentially enormous number of extracts.” According to the Examiner, “[t]he possible variations of extracts are limitless...because extraction techniques are often coupled in order to obtain a product...”

The Applicant respectfully submits that the Examiner has not met her initial burden of presenting evidence or reasoning to explain, by a preponderance of evidence, why persons skilled in the art would not recognize from the specification a description of the invention as claimed.

The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. Therefore, for example, the Examiner's general allegation of "limitless variations," like a general allegation of "unpredictability in the art," is not a sufficient reason to support a rejection for lack of adequate written description.

Factors to be considered in determining whether there is sufficient evidence of possession include: the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed genus is sufficient. (see *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

Regarding the claims that the Examiner asserts are "generics," the Applicant notes that what constitutes a "representative number" of species for a sufficient description is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.

The Applicant respectfully submits that the Examiner did not address any of the foregoing factors when issuing the §112, first paragraph rejection. In particular, the Applicant notes the Examiner's ability to readily list several methods of making extracts shows the high level of knowledge in the art, which would allow for disclosure of a very few number of species.

Moreover, the claim language at issue is expressly supported in the originally filed disclosure. For example, as stated in the specification under Field of the Invention, "The invention relates to a...tablet comprising a dried extract of red vine leaves, an excipient and a tablet film and the use thereof for the improvement of the blood circulation and/or the oxygen supply of the lower extremities."

Furthermore, extraction that is "aqueous" is not an essential feature of the invention. For example, nowhere in the specification is aqueous extraction described as being critical or essential to the invention.

In light of the foregoing, the Applicant respectfully requests that the §112, first paragraph, rejection of claims 1–4 and 6–16 be reconsidered and withdrawn.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ables. The Examiner asserts that Ables describes a coated tablet comprising atomized red vine extract in combination with excipients in a ratio of 1:1 (*i.e.*, 50% extract and 50% excipients). The Examiner further asserts that claim 1 is a product-by-process claim and the claimed feature "wherein the dried extract of red vine leaves has been

produced in a drying process comprising the step of adding at least a proportion of the excipient during the drying process” would not materially change the composition.

The Applicant respectfully disagrees with the Examiner and submits that the present invention as claimed is not anticipated by Ables. For example, Ables does not disclose or even suggest a tablet having enhanced stability comprising: up to 50% by weight of at least one excipient; and at least 50% by weight of a dried extract, the dried extract consisting essentially of ingredients of an aqueous extract of red vine leaves and a flow regulator comprising silica, wherein the tablet shows an enhanced stability. Therefore, the Applicant respectfully requests that the §102(b) rejection of claim 1 as being anticipated by Ables be reconsidered and withdrawn.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Esperester '727.

The Applicant respectfully disagrees with the Examiner and submits that the present invention as claimed is not anticipated by Esperester '727. For example, Esperester '727 does not disclose or even suggest a tablet having enhanced stability comprising: up to 50% by weight of at least one excipient; and at least 50% by weight of a dried extract, the dried extract consisting essentially of ingredients of an aqueous extract of red vine leaves and a flow regulator comprising silica, wherein the tablet shows an enhanced stability. Therefore, the Applicant respectfully requests that the §102(e) rejection of claim 1 as being anticipated by Esperester '727 be reconsidered and withdrawn.

Claims 1–16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esperester '727 in view of Struengmann. The Examiner asserts that Esperester '727 specifically suggests incorporation of carriers/excipients to the red vine extract during the drying process, but does not specifically teach the claimed combination of carriers/excipients. Struengmann is relied on for disclosure of conventional tablet additives. The Examiner concludes that it would be within the skill of the art at the time of the invention to identify the optimal concentrations of carriers/excipients.

The present application and Esperester '727 were, at the time the invention was made, subject to an obligation of assignment to the same organization, namely Boehringer Ingelheim International GmbH.

Therefore, Esperester '727 is disqualified as prior art for purposes of §103.

The Applicant respectfully requests that the §103(a) rejection of claims 1–16 as being obviated by Esperester '727 in view of Struengmann be reconsidered and withdrawn.

Claims 1–4 and 6–16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ables in view of Struengmann.

The Applicant respectfully disagrees with the Examiner and submits that the combination of Ables and Struengmann does not provide all of the features of the present invention as claimed. For example, the cited reference (either alone or in combination) do not disclose or even suggest a tablet having enhanced stability

comprising: up to 50% by weight of at least one excipient; and at least 50% by weight of a dried extract, the dried extract consisting essentially of ingredients of an aqueous extract of red vine leaves and a flow regulator comprising silica, wherein the tablet shows an enhanced stability. Therefore, the Applicant respectfully requests that the §103(a) rejection of claims 1–4 and 6–16 as being obviated by Ables in light of Struegmann be reconsidered and withdrawn.

Respectfully submitted,

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